

#### § 1308.34

paragraph (d) of this section for handling an application for an exemption which has been accepted for filing.

[56 FR 42936, Aug. 30, 1991; 57 FR 10815, Mar. 31, 1992, as amended at 62 FR 13968, Mar. 24, 1997]

#### § 1308.34 Exempt anabolic steroid products.

The list of compounds, mixtures, or preparations that contain an anabolic steroid that have been exempted by the Administrator from application of sections 302 through 309 and 1002 through 1004 of the Act (21 U.S.C. 822-829 and 952-954) and §§ 1301.13, 1301.22, and 1301.71 through 1301.76 of this chapter for administrative purposes only may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537.

[62 FR 13967, Mar. 24, 1997]

#### HEARINGS

#### § 1308.41 Hearings generally.

In any case where the Administrator shall hold a hearing on the issuance, amendment, or repeal of rules pursuant to section 201 of the Act, the procedures for such hearing and accompanying proceedings shall be governed generally by the rulemaking procedures set forth in the Administrative Procedure Act (5 U.S.C. 551-559) and specifically by section 201 of the Act (21 U.S.C. 811), by §§ 1308.42-1308.51, and by §§ 1316.41-1316.67 of this chapter.

#### § 1308.42 Purpose of hearing.

If requested by any interested person after proceedings are initiated pursuant to § 1308.43, the Administrator shall hold a hearing for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment or repeal of a rule issuable pursuant to section 201(a) of the Act (21 U.S.C. 811(a)). Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law. Additional information relating to hearings to include waivers or modification of rules, request for hearing, burden of proof, time and place, and final order

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are set forth in part 1316 of this chapter.

[62 FR 13968, Mar. 24, 1997]

#### § 1308.43 Initiation of proceedings for rulemaking.

(a) Any interested person may submit a petition to initiate proceedings for the issuance, amendment, or repeal of any rule or regulation issuable pursuant to the provisions of section 201 of the Act.

(b) Petitions shall be submitted in quintuplicate to the Administrator in the following form:

\_\_\_\_\_  
(Date)  
ADMINISTRATOR, DRUG ENFORCEMENT  
ADMINISTRATION  
*Department of Justice,*  
*Washington, DC 20537.*

DEAR SIR: The undersigned \_\_\_\_\_ hereby petitions the Administrator to initiate proceedings for the issuance (amendment or repeal) of a rule or regulation pursuant to section 201 of the Controlled Substances Act.

Attached hereto and constituting a part of this petition are the following:

(A) The proposed rule in the form proposed by the petitioner. (If the petitioner seeks the amendment or repeal of an existing rule, the existing rule, together with a reference to the section in the Code of Federal Regulations where it appears, should be included.)

(B) A statement of the grounds which the petitioner relies for the issuance (amendment or repeal) of the rule. (Such grounds shall include a reasonably concise statement of the facts relied upon by the petitioner, including a summary of any relevant medical or scientific evidence known to the petitioner.)

All notices to be sent regarding this petition should be addressed to:

\_\_\_\_\_  
(Name)

\_\_\_\_\_  
(Street Address)

\_\_\_\_\_  
(City and State)

Respectfully yours,

\_\_\_\_\_  
(Signature of petitioner)

(c) Within a reasonable period of time after the receipt of a petition, the